SENATE BILL 675
By Reeves

HOUSE BILL 667

By Hicks T

AN ACT to amend Tennessee Code Annotated, Title 56; Title 63 and Title 68, relative to a prescription drug donation repository program.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 5, is amended by deleting the part and substituting:

63-10-501. Part definitions.

As used in this part:

(1) "Cancer drug" means a prescription drug that is used to treat:

(A) Cancer or the side effects of cancer; or

(B) The side effects of a prescription drug that is used to treat cancer or the side effects of cancer;

(2) "Controlled substance" has the same meaning as defined in § 39-17-402;

(3) "Department" means the department of health;

(4) "Donor" means a person, including an individual member of the public and an entity legally authorized to possess medicine in the state in which the entity is located with a license or permit in good standing, including, but not limited to:

(A) A pharmacy or medical facility;

(B) A drug manufacturer or wholesaler; or

(C) A government agency or entity that is federally authorized to possess medicine, including, but not limited to:

(i) A drug manufacturer; repackager; relabeler; outsourcing facility; veteran affairs hospital; or FDA-authorized importer, as those entities are described in Sections 801 and 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 381 and 384), or similar provisions; and

(ii) A prison;

(5) "Eligible patient" means:

(A) An indigent, uninsured, or underinsured patient; or

(B) If an indigent, uninsured, or underinsured patient is unavailable, another person in need of donated prescriptions or supplies;

(6) "Eligible recipient" means an entity legally authorized to possess medicine with a license or permit in good standing in the state in which the entity is located, including, but not limited to:

(A) A wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, clinic, or prescriber office; or

(B) An entity participating in a drug donation or repository program pursuant to another state's law;

(7) "Indigent" means a natural person with an income that is below six hundred percent (600%) of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services;

(8) "Medical facility" means:

(A) A physician's office;

(B) A hospital;

(C) A health clinic;

(D) A nonprofit health clinic, including a federally-qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic, as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(E) A free clinic as defined in § 63-6-703;

(F) A charitable organization as defined in § 48-101-501; or

(G) A nursing home as defined in § 68-11-201;

(9) "Pharmacy" means a pharmacy as defined in § 63-10-204; or a similarly licensed entity in good standing in another state;

(10) "Prescription drug":

(A) Has the same meaning as defined in § 63-10-204;

(B) Includes, but is not limited to, over-the-counter medications and FDA-approved drugs labeled for investigational use; and

(C) Does not include controlled substances;

(11) "Supplies" means the supplies necessary to administer the prescription drugs donated pursuant to this part; and

(12) "Unopened tamper-evident packaging" has the same meaning as defined in United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements, including, but not limited to, unopened unit-dose, multiple dose, immediate, secondary, and tertiary packaging.

63-10-502. Prescription drug donation repository program.

(a) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing written notification to the department of the following:

(1) The name, street address, and telephone number of the pharmacy or medical facility, and a state issued license or registration number, including the name of the issuing agency;

(2) The name and telephone number of the responsible pharmacist who is employed, or under contract, with the pharmacy or medical facility; and

(3) A statement, signed and dated by the responsible pharmacist indicating that the pharmacy or medical facility meets the eligibility requirements and will comply with the program.

(b) The pharmacy or medical facility shall develop and implement standards and procedures to determine, based on basic visual inspection, that the prescription drugs appear to be unadulterated, safe, and suitable for dispensing.

(c) Except as provided in subsection (d), donated drugs must be in unopened tamper-evident packaging. However, drugs packaged in single-use doses may be accepted and dispensed when the outside packaging is opened if the single-unit dose packaging is undisturbed. Notwithstanding a law to the contrary, other drugs are not ineligible for donation.

(d) Specialty medications, including, but not limited to, cancer drugs, that are not in unopened, tamper-evident packaging may be donated.

(e) Donations of prescription drugs and supplies under the program may be made on the premises of an eligible recipient, or via mail to an eligible recipient, that elects to participate in the program.

(f) An eligible recipient may receive, accept, replenish, repackage, and store donated prescription drugs and supplies in accordance with this part.

(g) Donation and facilitation of a donation are not considered wholesale distribution, and a person donating or facilitating a donation does not require licensure as a wholesaler.

(h) Eligible recipients shall prioritize dispensing of donated prescriptions and supplies as follows:

(1) First, to an indigent patient;

(2) Second, to a patient who has no prescription insurance or cannot afford the out-of-pocket expenses for the drug prescribed; and

(3) Lastly, to another individual if an indigent, uninsured, or underinsured patient is unavailable.

(i) An eligible recipient shall not charge or collect fees from an eligible patient for prescriptions or supplies dispensed pursuant to the program. However, an eligible recipient may charge a handling fee for each donated drug or supply that is dispensed.

(j) An eligible recipient may charge fees, including, but not limited to, a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefits managers, drug manufacturers, veterans affairs hospitals, and government agencies.

(k) A medical facility or pharmacy that receives donated prescription drugs or supplies may distribute the donated prescription drugs and supplies to another eligible recipient for use pursuant to the program or to similar repository programs in other states.

(l) Participation in the program is voluntary.

63-10-503. Accepting and dispensing of donated prescription drugs and supplies.

Prescription drugs and supplies may be accepted and dispensed under the prescription drug donation repository program in accordance with the following:

(1) A licensed pharmacist employed, or under contract, with the program inspects donations prior to dispensing to determine if the donations are suitable for dispensing pursuant to this section;

(2) Eligible recipients store inventory in a secure area under environmentally appropriate conditions;

(3) Eligible recipients redact donor information from the packaging;

(4) Donated inventory is physically or electronically separated from non-donated inventory;

(5) Prior to dispensing a donated drug:

(A) An eligible recipient inspects the drug to determine that it has not been adulterated; and

(B) The drug is repackaged into a new container or all previous patient information and pharmacy labeling is redacted or removed from the donated container;

(6) Donated inventory may be used to replenish purchased inventory in compliance with applicable provisions of 42 U.S.C. § 256b and regulations promulgated pursuant to that statute;

(7) Donated inventory may be repackaged. Repacked drugs must be labeled with the drug name, strength, and expiration date; notwithstanding a law to the contrary, other labeling requirements are not required on the drug packaging;

(8) Eligible recipients maintain an electronic inventory of accepted donations that includes the drug name, national drug code number or manufacturer, quantity, and date of donation;

(9) An identifier or bar code may be used in place of information required by law for a record or label if the identifier or bar code allows for that information to be readily retrievable;

(10) Eligible recipients return or destroy donated drugs or supplies that are not suitable for dispensing and make a record of the return or destruction that includes the drug name, strength, quantity, method of destruction, and date of destruction. Other records of disposal are not required;

(11) Eligible recipients dispose of donated prescriptions and supplies by returning the donated prescriptions and supplies to the donor, transferring the donated prescriptions and supplies to a reverse distributor, or incinerating the donated prescriptions and supplies in an incinerator that is approved by the federal environmental protection agency;

(12) The record of transaction history for a drug is maintained, beginning with the donor of the drug, including all prior donations, but not including information that is not required by law to be placed on the drug's label;

(13) Eligible recipients dispense in compliance with all applicable federal and state laws and regulations for dispensing, labeling, packaging, and recordkeeping;

(14) An expiration date is required on all dispensed drugs and supplies. The expiration date must be brought forward to the filled prescription. If multiple packaged donated drugs are used to fill a single prescription with varied expiration dates, then the shortest expiration date must be used for the dispensed prescription. A drug or supply must not be dispensed after its expiration date;

(15) Dispensed drugs must not expire before the end-use date by the patient based on the prescriber's directions;

(16) Controlled substances are not accepted for donation. Controlled substances must be disposed of pursuant to regulations promulgated by the federal drug enforcement administration (DEA). Destruction is accomplished by the use of a reverse distributor or following current regulations promulgated by the DEA regarding destruction of controlled substances;

(17) Prescription drugs that are part of a risk evaluation and mitigation strategy program of the federal food and drug administration must not be accepted for donation;

(18) Prior to the first donation from a new donor, an eligible recipient must verify and record the following:

(A) The donor meets the definition provided in § 63-10-501;

(B) The donor's name, address, phone number, and license number, if applicable; and

(C) The donor will only make donations of prescription drugs and supplies in accordance with this part;

(19) Records other than those described in this section are not required;

(20) Records required pursuant to this section must be retained in physical or electronic format for a period of three (3) years. A donor or eligible recipient may contract with one another or a third party to create or maintain records on each other's behalf; and

(21) When performing an action associated with this program or otherwise processing donated medicine for tax, manufacture, or other credit, an eligible recipient is considered to be acting as a returns processor and shall

comply with all recordkeeping requirements or nonsaleable returns pursuant to federal law.

63-10-504. Immunity and exemption.

(a) A drug manufacturer acting reasonably and in good faith is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (c), a person other than a drug manufacturer subject to subsection (a), acting reasonably and in good faith, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part and is exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(c) The immunity and exemption provided in subsection (b) does not extend to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

63-10-505. No restriction on use of samples.

This part does not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

63-10-506. Resale of prescription drugs not authorized.

This part does not authorize a person to resell prescription drugs.

63-10-507. Authority.

The program is solely governed by this part. This part supersedes a law or rule inconsistent with this part.

SECTION 2. If a provision of this act or its application to any person or circumstance is held invalid, then the invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act shall be severable.

SECTION 3. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. This act takes effect January 1, 2024, the public welfare requiring it.